

REMARKS

Claims 1-13, 15, and 18-25 were pending in the application. Claims 23 and 24 have been cancelled, and claims 1, 12, 18 and 19 have been amended. Accordingly claims 1-13, 15, and 18-22 and 25 will be pending upon entry of the foregoing amendments. Support for these amendments may be found throughout the specification and the claims as originally filed. For example, support for the amendment of claim 1 may be found in the specification at least at page 4, lines 2-15, and at page 7, lines 18-22. Support for the amendment of claims 12 may be found in the specification at least at page 9, lines 5-8. Accordingly, *no new matter has been added*.

Any amendments to and/or cancellation of the claims should in no way be construed as acquiescence to any of the rejections and was done solely to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed or as previously pending in this or a separate application(s).

Previous Objections and Rejection

Applicants gratefully acknowledge the Examiner's acceptance of the declaration for patent application listing inventors Balmain and Zhu and signed by Dr. Zhu, as well as the withdrawal of all of the rejections set forth in the previous action.

Claim Objections

Claim 23 was newly objected to on the ground that it fails to further limit the subject matter of claim 22 from which it depends. Applicants submit that claim 23 has been cancelled, therefore obviating this rejection.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-13, 15 and 18-25 were rejected for failing to comply with the written description requirement on the ground that the specification does not provide any promoters other than those containing a p53 binding sequence that are upregulated in non-tumor cells relative to tumor cells carrying a mutant p53 allele, and does not disclose any examples of promoters that are upregulated in non-tumor cells relative to tumor cells carrying a mutant p16 allele. Further, the Office Action further states that "while the

claims recite 'tumor cells carrying a mutant p53 or p16 allele', the claims require no relationship between the nature of the p53 or p16 mutation and the tumorigenicity of the cells". (Paper 29 at page 5)

Applicants respectfully traverse this rejection. "Written description may be satisfied through disclosure of relevant identifying characteristics, i.e., structure, other physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112, First Paragraph Written Description Requirement*. Moreover, "[a] specification may, within the meaning of 35 U.S.C., § 112, First Paragraph, contain a written description of a broadly written claimed invention without describing all species that claim encompasses." *Utter v. Hiraga*, 845 F.2d 993, 6 USPQ2d 1709 (Fed. Cir. 1988).

The specification teaches that the promoters possess certain functional characteristics, i.e., promoters that are suppressed in non-tumor cells relative to tumor cells for the first nucleic construct, and promoters that are up-regulated in non-tumor cells relative to tumor cells for the second nucleic acid construct. The specification also provides working examples of promoters that are suppressed or activated by wild-type or mutant p53. Further, the specification provides guidance which would allow the skilled artisan to test any promoter to determine whether it has the required characteristics (e.g., at pages 14-15, and in the assays disclosed in the examples at pages 28-45).

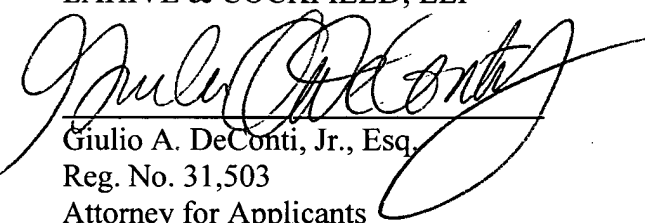
Accordingly, Applicants respectfully submit that such guidance is sufficient to meet the written description requirement. However, solely in the interest of expediting prosecution of the application, claim 1 has been amended to specify that the second promoter comprises a p53 binding site, and further that the promoter is upregulated in normal cells relative to tumor cells in which wild-type p53 tumor suppressor function has been abrogated in the tumor cells. Further, claim 12 has now been amended to remove reference to the CMV promoter. In view of these amendments, reconsideration and withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. §112, Second Paragraph

Claims 18 and 19 were rejected as indefinite on the ground that they depend from cancelled claim 17. Applicants respectfully submit that these claims have been amended to correct their dependency, thereby obviating this rejection.

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. If a telephone conversation with Applicants' Attorney would expedite prosecution of the above-identified application, the Examiner is invited to call the undersigned at (617) 227-7400.

Respectfully submitted,
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